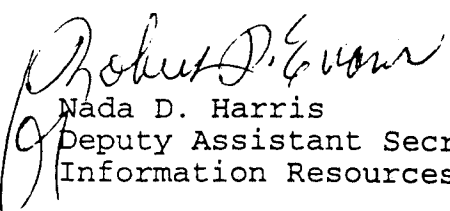



SUPPLY, PROCESSING, AND DISTRIBUTION (SPD) OPERATIONAL REQUIREMENTS

1. **REASON FOR ISSUE.** This handbook is issued in accordance with the new directives management policy and procedures and implements policy contained in VA Directive 7176. It is to be used with VA Directive 7176, the SPD Handbook, and the SPD Training and Instructor's manuals.
2. **SUMMARY OF CONTENTS/MAJOR CHANGES.** This handbook provides guidance and procedures pertinent to the operational requirements and responsibilities of SPD activities.
3. **RESPONSIBLE OFFICE.** Office of the Deputy Assistant Secretary for Acquisition and Materiel Management (90).
4. **RELATED DIRECTIVE.** VA Directive 7176.
5. **RESCISSION.** VA Manual MP-2, Subchapter E, Part 108-76 in its entirety.

CERTIFIED BY:

**BY DIRECTION OF THE SECRETARY
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SUPPLY, PROCESSING, AND DISTRIBUTION (SPD) OPERATIONAL REQUIREMENTS

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PART 1. DEFINITIONS

The following terms, as they relate to SPD operations, have the meanings set forth below:

1. **Aeration.** Exposure to the free actions of circulating air with the use of a mechanical aeration device utilizing filtered air at elevated temperatures.

2. **Biological Indicator.** A calibration of microorganisms (of known high resistance to the mode of sterilization being monitored), in or on a carrier and enclosed in a protective package, that serves to demonstrate that sterilization conditions were met. (Also known as biological monitor or biological spore test.)

3. **Bowie-Dick Type Test.** A test to monitor the adequacy of air removal from the chamber and porous load during the prevacuum phase and to detect the presence of air leaks in prevacuum sterilizers. The test is for prevacuum (high vac) sterilizers only.

4. **Chemical Indicator.** A physical/chemical device used to monitor one or more parameters of the sterilization process in order to assure that factors such as packaging, loading, and/or sterilizer functioning do not prevent sterilization. The chemical indicator usually consists of a sensitive chemical or ink dye, the sensitivity of which may vary from product to product.

5. **Containerized Sterilization System.** A specially designed container system (pre-formed rigid container) for sterilization, transportation, storage, and presentation of surgical instruments. When sealed, the container assembly allows penetration of air and steam (or gas) into and out of the container for sterilization of its contents.

6. **Contamination.** State of being soiled or rendered unsafe for use by contact with infectious material.

7. **Decontamination.** The destruction or removal of living organisms to some lower level, but not necessarily to zero.

8. **Disinfectant.** A chemical agent that kills or inactivates vegetative bacteria, fungi, and some viruses, but not spores.

9. **Dust Cover.** An additional protective post sterilization overwrap used to assist in maintaining the sterility of a product by protecting it against the environment. Usually made of plastic two to three mils thick, the dust cover does more than protect from dust; it also serves as a barrier to contaminants such as moisture, lint, or vermin.

10. **Expiration Date.** The date which is calculated by adding to the date of sterilization the shelf life of a sterilized product (see Shelf Life).

11. **Impervious.** Those wrapping materials which do not permit the free passage of air, water, or other contaminants through their walls under normal handling and storage conditions.

12 **Implantable Device.** A device that will be surgically implanted and totally contained in the body. Examples: Orthopedic hardware items such as pins, screws, nails, rods, and hardware used in total joint system replacement; prosthetic heart valves; central nervous system reservoirs and drains; and breast prostheses. Drains and tubes used temporarily after surgery are excluded.

13. **Load Control Number.** A combination of numbers by which a particular group of products may be traced to a particular sterilization process.

14. **Muslim.** All cotton, 140-thread-count fabric used as a sterilization wrapping material.

15. **Post-sterilization.** Any or all of the activities taking place after sterilization of materials or equipment.

16. **Protective Clothing.** Protective clothing is defined as surgical cap, fluid-repellent gown or apron, jumpsuit, mask, eye protection, facial hair covering, gloves, and fluid-repellent shoe covers. The function being performed will determine the specific items of protective clothing required to furnish adequate protection to the employee, visitor, and patient. Protective clothing appropriate for each area or function will be defined in the local SPD Policy and Procedures Manual.

17. **Shelf Life.** The period of time during which sterility of a sterilized product is assumed to be maintained.

18. **Sterile.** The state of being free from all living microorganisms; in practice, usually described as a probability function.

19. **Terminal Sterilization.** The final sterilization process prior to issuance of sterile supplies for consumer use.

PART 2. QUALITY CONTROL**1. 201 Sterilization Records and Controls**

a. A six digit control number will be assigned for each sterilizing cycle. The first digit will identify the numerical designation of the sterilizer being used. The second, third, and fourth digits will indicate Julian calendar day of the year, i.e., 001 through 365 days. The fifth and sixth digits will indicate the number of times the sterilizer operated during a 24-hour period.

b. Each package or item terminally sterilized will be labeled prior to sterilization with the common name of the package contents or item and initialed by the employee who prepared the package or item for sterilization. All sterilizer cycles will be recorded and contents of load listed as to General Category.

c. The control number and expiration date will be affixed to each package or item intended for use as a sterile product after the mechanical and chemical indicators have been checked after sterilization. Color coding will be used to assist in stock rotation but will not be substituted for the actual assigned expiration date. Markings will not be made directly on the wrapper by either ball point or felt tip pens as they may puncture or strike through the wrapper and contaminate the contents. A mechanical labeling device is recommended.

d. A register will be established for all sterilizing equipment without an automatic recording device. The following information will be recorded by the sterilizer operator for each sterilizing cycle:

- (1) Sterilization date
- (2) Contents of load as to general category (e.g., linen packs, instruments, respirator care supplies)
- (3) Control number assigned
- (4) Sterilization temperature
- (5) Actual length of sterilizing cycle at desired temperature (exposure period)
- (6) Remarks (e.g., condition of load, sterilizer breakdown)
- (7) Signature of sterilizer operator

e. For all sterilizers equipped with a recording device, the appropriate chart or digital printout will be examined and signed by the sterilizer operator after each cycle, before any items are removed from the sterilizer to verify adequate temperature and duration of exposure. Sterilizer malfunctions or suspicious operation, as indicated by the recording device, will be reported immediately to the Chief, SPD, who will make the final determination on the use of that sterilizer, initiate an appropriate request for service, and implement reprocessing routines for the load in question, if necessary.

2. 202 Sterilization Process Controls. All reusable medical/surgical devices used for patient care (direct or indirect) should be sterilized in the SPD section. Reusable devices are items which are manufactured for reuse or which the manufacturer has provided specific written resterilization instructions. If, for some reason, (due to staff, limited equipment, required short turnaround time) sterilizers are located in other sections of the medical facility, they will be monitored mechanically and with biological indicators. All records will be kept for 36 months (this includes all sterilizers in the medical facility used in conjunction with patient care, i.e., lab, dental). A report of all tests and results will be submitted through the Chief, SPD, to the Infection Control Committee monthly.

a. External Indicators. A strip of the appropriate sterilizer indicating tape must be affixed externally to each package or item prior to terminal sterilization, unless an indicator is already a part of the packaging material. This indicator tape, label, or legend indicator visually denotes that the package or item has been exposed to the physical conditions of a sterilizing cycle, but will not be considered through the appropriate sterilizer cycle.

b. Internal Indicators. The use of internal chemical indicators is optional based on local consideration of the costs versus the benefits. In determining the need for use of internal chemical indicators, the Chief, SPD, must carefully assess the sterility assurance program. Assistance may be obtained from the technical information report provided by the Association for the Advancement of Medical Instrumentation (AAMI) titled, *Selection and use of Chemical indicators for Steam Sterilization Monitoring*. The person recovering the indicator from the sterile pack must be adequately trained in the interpretation of the specific indicator used. Internal chemical indicator are not sterility indicators and will not be used as a substitute for biological indicators. If internal indicators are used, written supporting data from the manufacturer regarding reliability, safety, efficiency, performance characteristics, instructions for use, and interpretation of results must be maintained on file in SPD. Instructions for appropriate use, placement, and interpretation of results must be communicated to the product users by the Chief, SPD, and revised, as necessary.

c. The SPD Handbook will define all types of chemical indicators used in SPD and provide detailed procedures for their use.

3. 203 Sterilizer Tests

a. A Bowie-Dick type test, to determine adequacy of air removal from chamber and porous load, will be performed daily for each pre vacuum (high vac) steam sterilizer. The test results will be recorded on the sterilizer recording chart. If commercially prepared test products are used, the test will be carried out according to the written instructions of the manufacturer of the system used. In the absence of commercial products, test packs will be prepared according to the description of the Bowie-Dick test described in "Principles and Methods of Sterilization in Health Sciences" by John J. Perkins.

Sterilizer operators must be trained in test preparation and interpretation. Test results must be documented and maintained with the records of that sterilizer.

b. A standard procedure will be instituted by the Chief, SPD, and, when necessary, coordinated with Laboratory Service for the routine challenge of each sterilizer by means of a commercially prepared, self-contained, biological monitoring system. *Bacillus stearothermophilus* spores will be used to evaluate steam sterilizers. *Bacillus subtilis* spores will be used to evaluate dry heat and gas sterilizers. One control from each lot of biological tests will be used for gas and steam. Each steam or dry heat sterilizer will be tested a minimum of once daily (on days that the sterilizer is utilized.) Gas sterilizers will be tested with each sterilizing cycle. More frequent testing will be accomplished on an as needed basis for record purposes (i.e., after sterilizer repairs, when evaluating sterilization new products, packaging materials). Self-contained biological monitoring system test results may be interpreted and are recommended to be by the Chief, SPD, or designee, in strict conformance with the manufacturer's instructions. Advice of Laboratory Service will be solicited on any questionable results following use of a self-contained biological monitor. Written test results of all biological monitoring will be maintained with the sterilizer records and kept on file in SPD for 36 months.

c. All steam and ethylene oxide gas sterilization loads containing implantable devices or intravascular materials will be monitored with the appropriate biological indicator. After sterilization, these devices will be held in quarantine by SPD and will not be used until the spore test is found to be negative (after 48 hours). Early release for use will be permitted by the Chief, SPD, only after documentation is obtained from the Chief of Staff, or designee. Implantable devices will not be sterilized by flash steam sterilization.

d. When a positive biological test result is obtained, the biological indicator will be immediately submitted to the microbiology laboratory for a presumptive organism identification. This helps to determine if the living microorganism is the indicator test microorganism (indicating inadequate sterilization conditions) or an accidental contaminant that could have been introduced after the load was removed from the sterilizer. If spores are not killed in routine spore tests, the proper use and function of the sterilizer will immediately be checked. All items sterilized in a sterilizer since the last negative test will be recalled for a positive test. The sterilizer in question must immediately be rechallenged with biological indicators. If spore tests remain positive after proper use of the sterilizer is documented and an operational inspection has been performed, use of the sterilizer will be discontinued and it will be serviced.

e. Positive biological indicator results will be reported immediately, in writing, by the Chief, SPD, to the Chief of Staff; Chief, Surgical Service; the Service responsible for the SPD Section; and the Infection Control Committee. The report will include the time

and date of the questionable sterilizer cycle; description of the sterilizer and load, with reference to the appropriate load control number; time and date of notification of positive results; laboratory identification of the organism; and any other pertinent information. The Chief, SPD, will make recommendations to the Chief of Staff; Chief, Surgery Service; and the Service responsible for the SPD Section, for further action as considered appropriate or necessary. In all cases, the sterilizer in question must immediately be rechallenged with biological indicators.

f. Not later than the 10th day of each month, a written report of biological spore tests conducted on all sterilizers during the previous month will be submitted to the medical facility Infection Control Committee by the Chief, SPD. This report will include the total number of biological tests and controls conducted on each sterilizer and the results of that testing. The Chief, SPD, is responsible for biological monitoring and reporting on all sterilizers in the medical facility used for sterilizing any item used for direct or indirect patient care. For sterilizers that are located in areas other than SPD, the Chief, SPD, will provide training and assistance as needed to complete the monitoring and reporting described above.

4. 204 Quality Control Records. Quality control measures must be documented. All sterilizer recording charts, digital printouts, registers, biological and Bowie-Dick test results, reports, and all other associated quality control documentation will be maintained for at least 36 months. The Chief, SPD, will ensure that all equipment used in the SPD section functions and all patient care equipment assigned to SPD is scheduled for routine preventive maintenance.

5. 205 Committee Membership. It is recommended that the Chief, SPD, be a member of the facility's Infection Control and Commodity Standards Committees.

PART 3. STERILIZATION METHODS**1. 301 Steam Sterilization**

a. Saturated steam under pressure will be the method of sterilization for all items which will tolerate the temperature, pressure, and moisture. Unless specifically contraindicated in writing by the device manufacturer, steam sterilization will be the method of choice.

b. The sterilizer manufacturer's operational recommendations will be followed.

c. A record must be kept on all steam sterilizer malfunctions and repairs.

2. 302 Ethylene Oxide (EtO) Gas Sterilization

a. Sterilization by EtO will be limited to medical supplies and devices that are sensitive to extremes in temperature, pressure, or moisture.

b. The sterilizer manufacturer's operational recommendations will be followed.

c. The Chief, SPD, will list all medical supplies, devices, and equipment that require EtO sterilization and will review and update the list annually or more frequently, if necessary. The list will be approved by the Chief of Staff and maintained in SPD. Review will be directed at eliminating the use of EtO sterilization for material and equipment that can be effectively steam sterilized.

d. All EtO sterilization will be centralized in the SPD section, under the direction of the Chief, SPD.

e. A properly installed and vented EtO sterilizer may be utilized in dental clinics only when the services of SPD are unavailable:

f. In-service programs on the EtO process will be conducted as directed in 29 CFR 1910.1047.

g. No equipment, supplies, or items, other than gas sources in use, will be stored in the sterilizer maintenance space, access space or recess space (e.g., cleaning equipment, supplies, spare parts).

h. Records must be kept on all gas sterilizer malfunctions and repairs.

i. Accidental excessive exposure to EtO must be recorded as an accident, and a report must be filed.

3. 303 Ethylene Oxide (EtO) Aeration

a. All EtO sterilized items will be properly aerated before handling or use in an aeration cabinet specifically designed for this function. The use of sterilizer/aerator combinations is highly encouraged.

b. The Chief, SPD, will establish written minimum aeration periods for all EtO sterilized items. Specific aeration recommendations should be obtained from the device manufacturer.

c. The following is the minimum aeration time for eliminating EtO residuals in the absence of specific recommendations by the device manufacturer: Aeration in an approved cabinet at 50 degrees Centigrade - 12 hours (122 degrees Fahrenheit).

d. When in doubt about aeration requirements for a particular device, the time shown in paragraph c of this section may be followed (12 hours); however, some materials may require even longer periods of aeration so the device manufacturer should be consulted for specific recommendations. Ambient or room temperature aeration is not authorized.

4. 304 Steam/Vapor Sterilization

a. Steam/vapor sterilization (steam, formaldehyde, alcohol) will be limited to dental areas where SPD cannot provide sterilization support.

b. All steam/vapor will be monitored as outlined for steam Section 201 of this handbook.

5. 305 Dry Heat Sterilization. Sterilization of anhydrous oils, greases, petroleum jelly, powders, or similar products will not be conducted in the medical facility.

6. 306 Peracetic Acid Sterilization

a. Sterilization by Peracetic Acid will be limited to medical devices that are sensitive to extremes in temperature and pressure.

b. This method of sterilization for items used in surgery will be used only as a flash sterilizer and only when needed for an emergency when normal (steam or EtO) sterilization cannot be used.

c. Items that should be sterilized between patient use, such as non-invasive flexible endoscopes, but do not have to be sterile for use, should be cleaned and processed in SPD.

7. 307 Gas Plasma Sterilization. Plasma sterilization is a future method of sterilization that is in early testing and is being evaluated for SPD use at this time.

8. 308 Liquid Chemical Sterilization (Glutaraldehyde, Phenolic Compounds, Alcohols, Quats, and Iodine)

a. There is no present method available that allows the user to microbiologically test the efficacy of a liquid chemical sterilization process within the health care facility. Liquid chemical and cold liquid sterilization processes, therefore, may be employed for high level disinfecting only. The manufacturer's recommendations for the solution used will be followed.

b. Terminal sterilization by this method is not authorized. After appropriate cleaning, reusable respiratory therapy and anesthesia tubing, parts, and associated components processed in SPD will be gas or steam sterilized and adequately aerated as appropriate.

9. 309 Solutions. SPD will not manufacture or sterilize parenteral or irrigating solutions. Hospitals are not equipped to monitor fluids to assure sterility and nonpyrogenicity in accordance with current Food and Drug Administration requirements.

PART 4. SUPPORTING ASEPTIC TECHNIQUES

1. 400 Scope. This part prescribes supporting aseptic techniques which will help to ensure that all medical supplies are decontaminated and processed under the best possible conditions for maximum safety and protection of patients, employees, and visitors.

2. 401 Restrictive Techniques

a. The use of tobacco products, eating, drinking, or the storage of food items (including beverages) will not be permitted in SPD where the processes of decontamination, sterilization, supply storage, data equipment handling, or dispatching of patient care supplies or equipment are performed.

b. Portable fans will not be authorized for use in SPD.

c. Traffic in SPD is restricted to authorized personnel. Only persons with official business, and when accompanied by an appropriate supervisor or designee, will be authorized entrance to SPD. Individuals seeking entrance will wear suitable protective clothing (and dispose of) as specifically defined in the local SPD Policy and Procedures Manual, Chapter 9. Personnel performing equipment repair, building maintenance, and housekeeping activities will wear prescribed protective clothing while performing duties in areas of SPD where special attention to epidemiological precautions is required. All protective clothing will be removed and properly stored or disposed of, as appropriate, prior to leaving the area.

d. Single-use disposable medical devices will not be resterilized and/or reused. Reusable devices should be purchased if the intent is to resterilize and reuse them. If a package containing an expensive sterile disposable device is opened and the item is not used, the manufacturer should be contacted for either the possibility of exchange or specific written re-sterilizing instructions. In the absence of either service provided by the manufacturer, the device will not be repacked or over-wrapped and resterilized. New reprocessing procedures, or changes to current procedures, must be reviewed by OA&MM SPD program officials prior to implementation.

e. Random samples of sterile items procured commercially or processed in-house by SPD will not be subjected to sterility testing except as requested by the Infection Control Committee for evaluation of specific problems.

f. Staples, paper clips, pins, tape (other than indicator tape), and similar items will not be used in conjunction with the packaging, sterilization, or storage of supplies as they may promote accidental contamination. Rubber bands will not be used to band items together for sterilization, storage, or delivery. This applies to items processed in-house, as well as sterile supplies from a commercial source.

g. Temperature and humidity will be controlled in all areas of SPD. Temperature will be maintained between 65 and 72 degrees. Humidity will be maintained between 35 and 75 percent.

3. 402 Procedural Techniques

a. All soiled reusable supplies and portable or mobile equipment will be transported from the using area to the decontamination area in SPD in covered carts or containers. Items too large to be placed in a covered container will be covered with a waterproof bag or other suitable material while in transit. Collection containers or bags for holding or transporting soiled reusable supplies must be made of material that can be properly decontaminated or incinerated following use.

b. All soiled supplies and equipment being removed from user areas will be considered contaminated and handled with regard to the Universal Precaution techniques recommended by Centers for Disease Control (CDC) guidelines.

c. Personnel engaged in the collection or removal of soiled/contaminated supplies and equipment, as well as those individuals working in the decontamination or preparation areas, will wear suitable protective clothing as indicated below:

(1) Decontamination Area

- (a) Scrub Suits (Operating Room Type)
- (b) Head/Hair Covers
- (c) Safety Glasses/Goggles/Face Shields
- (d) Surgical Face Masks
- (e) Long Cuffed Rubber/Vinyl Gloves (No Surgical Gloves)
- (f) Impervious Gown
- (g) Impervious Shoe covers (Not Disposable Paper Shoe Covers)
- (h) Nail polish and/or false fingernails will not be worn.
- (i) Jewelry will be limited to wedding rings

(2) Decontamination Pickup

- (a) Cover Gown
- (b) Exam gloves will be changed after each pick-up location.

(3) **Nurse Servers.** Decontamination pick-up at Nurse Servers will be the same as the Decontamination Area, but protective clothing must be changed from one floor to another.

(4) Preparation Area

(a) Scrub suit with long sleeves (if short sleeve tops are issued throughout the medical facility, a warm-up jacket or gown must be provided with long sleeves to cover the arms.) Attire worn in this area must not be worn in other areas of SPD or the medical facility without a long sleeve cover coat.

(b) Head, Beard, and Mustache Covers must be worn.

(c) It is recommended that shoes be dedicated for use in SPD or the medical facility and maintained in employee lockers.

(d) When SPD personnel are responsible for collecting and transporting soiled linens, it will be done in such a manner that avoids spreading bacteria to the environment. Soiled linen will be considered contaminated and handled with regard to Universal Precaution techniques recommended by CDC guidelines. Linen not placed in appropriate containers should not be transported from the site of collection. A separate set of containers will be used for transporting clean linen and soiled linen.

(e) After use, disposable needles, syringes, and sharps will be placed in designated puncture-resistant containers by the user. These containers will be sealed and removed by personnel responsible for the overall waste management program at the facility. Needle clipping devices will not be furnished by SPD to any area of the facility. Discarded disposable needles, syringes, and sharps, will not be processed in SPD prior to final disposal. Equipment for sterilization, disinfecting, grinding, compacting, or incineration of infectious waste materials, including disposable needles, syringes, and sharps will not be located in SPD because of the potential for cross-contamination. Only reusable patient care supplies and equipment will be processed in SPD.

(f) In cooperation with Environmental Management Service (EMS), a written daily cleaning schedule for SPD areas will be developed, implemented, and enforced. Cleaning encompasses wet mopping or wet vacuuming of floors with a suitable germicide at least once a day, and more often if necessary. Walls, ceilings, vents, and filters should be cleaned at least monthly. Sweeping or dry dusting is prohibited in SPD. Dedicated cleaning equipment will be provided for, and maintained in, the SPD decontamination area. This equipment will not be used in other areas of SPD or the facility. Dedicated sanitation/cleaning materials will be used in the clean areas of SPD. There will be written procedures for the cleaning and sanitizing of work surfaces, floors, utensils, and equipment used in SPD functions. EMS personnel will never go from the decontamination area to the preparation area while cleaning. Cleaning should start in the sterile storage area, proceed to the preparation area, and then to the decontamination area.

(g) All patient care equipment will be cleaned, disinfected, or sterilized, as appropriate, prior to reuse. Mobile or portable equipment will be covered with a clean dust cover for storage. Cleaning, disinfecting, or sterilization will be in accordance with the equipment manufacturer's instructions. All equipment will be checked to ensure that it functions correctly prior to reissue.

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(h) Specific supply delivery and collection points will be designated in each area serviced by SPD. SPD delivery of supplies, equipment, or medical gases directly into a patient room where a member of the medical staff is not present will be at the discretion of the Chief, SPD.

(i) Any SPD employee reporting for duty who is feeling ill or may know that they have an infection must report this condition to the Chief, SPD. A written policy shall be developed by the Chief, SPD, in cooperation with the infection control committee and the employee health physician, for the provision of treatment, temporary change of duty assignment, or approval of sick leave for the employee, if required.

(5) Distribution/Sterile Stores. The specific attire of choice for this area is the regular SPD uniform consisting of white pants and blue zipper front smock. The purpose of specific SPD attire is to prevent the transmission of bacteria, and only medical facility issued clothing will be worn in the area. Laundering of SPD uniforms will be accomplished by the medical facility, and personally owned uniforms or articles of clothing will not be authorized.

4. 403 Physical Restrictions

a. Physical separation of soiled from clean areas must be maintained to assist in the prevention of cross-contamination. Separation of clean from soiled also applies to patient care supplies and equipment in SPD and throughout the medical facility.

b. If the same individual must handle the supplies before and after decontamination, that person must complete the following actions prior to performing assignments in other areas:

(a) Remove the decontamination attire (e.g., cap, gown/apron, gloves).

(b) Change into appropriate clean attire.

(c) Wash and dry hands thoroughly (a shower is recommended).

c. To maintain and control a clean environment in SPD, there must be no exposed pipes, ducts, or cables to collect lint and dust. Light fixtures must be recessed.

PART 6. STERILE SUPPLY TECHNIQUE

1. 601 Wrapping Materials

a. Materials for packaging or wrapping supplies for sterilization are limited to those products specifically designed and manufactured for sterilization of medical devices.

b. Disposable wrapping materials are single use items and must not be reused. Muslin wrappers must be laundered, inspected, and delinted between each use. Sterilizing containers will be processed in strict accordance with the manufacturer's recommendations. Aluminum foil may be used in dry heat sterilizers only. Paper/plastic peel-down pouches must be placed loosely in the sterilizer and on edge to facilitate removal of air and penetration of the sterilant. Wire-type baskets may be used to keep packages in position.

c. All items wrapped in muslin, paper, spun-bond fabrics, or non-woven wraps will be sequentially wrapped (a wrapped package within a wrapped package) in two wrappers of the selected wrapping material, but not necessarily the same materials. A double-thickness muslin wrapper is considered a single wrap. Stitching in the body of the wrapper is not acceptable.

d. Plastic wrapping materials and combination plastic/paper laminated peel down packaging are considered to be impervious. One wrapper of these materials is sufficient. However, it is easier to introduce the product to a sterile field if double peel packed.

e. Post sterilization wraps (dust covers) may be sealed with pressure sensitive tape or heat seals.

f. Before being placed in dust covers, steam sterilized packages must be cool and dry; gas sterilized items must be adequately aerated. A dust cover, if used, must be applied to a thoroughly cooled, dry package at the time the package is removed from the sterilizer or aerator cart. Caution must be taken to avoid premature contamination by excessive handling. The dust cover must be clearly marked to indicate that it is a post sterilization wrap or dust cover so that the outside of the inner wrap will not be mistakenly considered sterile. Identification of package contents, load control number, and expiration date must be clearly visible through the dust cover. Once the package is removed from the dust cover (even though not opened for use), the extended shelf life provided by the post sterilization wrap is no longer valid.

g. Sterilization container systems will be processed in strict accordance with the product manufacturer's recommendations. Containerized systems using valve biobarrier configurations will not be used for gas sterilization because the valve does not open in standard aerators and the contents of the container cannot be aerated. Filtered containers can be aerated, however, and can be used in both prevacuum steam and ethylene oxide gas sterilization cycles. The container manufacturer's supporting data concerning sterilization

cycle compatibility and specific instructions for use must be obtained before using sterilization containers for in-hospital packaging. The test data and manufacturer's instructions for use will be maintained on file in SPD. Local procedures for use will be developed and incorporated in the SPD Policy and Procedures Manual. SPD personnel will be thoroughly trained in the care and use of sterilization containerized systems prior to operating a sterilization cycle containing such a system.

2. 602 Size and Weight Limitations

a. Linen packs should not exceed 12 x 12 x 20 inches in size and weigh approximately 12 pounds to ensure proper sterilizer loading and allow steam penetration. Packs with a density greater than 7.2 pounds per cubic foot increase the risk of not achieving complete load sterilization. The mathematical formula for computing pack density is:

$$\frac{\text{pack weight (pounds)} \times 1728}{\text{pack length} \times \text{width} \times \text{height (inches)}} = \text{pack density (pounds per cubic foot)}$$

b. The average instrument set should not exceed 16 pounds in weight or the weight specified by the sterilizer manufacturer to achieve proper sterilization. Heavy, dense sets may not allow adequate sterilization and drying in the specified time because of condensation, slower heat rise, and slower heat transfer.

c. Instruments processed in a sterilizing container system should not exceed the weight specified by the container manufacturer. This does not include the weight of the container.

3. 603 Handling Sterilized Items

a. Handle sterile products with extreme care to prevent contamination.

b. Sterile products, when they are compressed, or when the packaging or wrapper is torn or appears to be wet, should be considered contaminated and returned to the decontamination area for reprocessing. If there is any doubt about the sterility of an item, it must be totally reprocessed and resterilized before it should be considered safe for use.

c. Sterile products, as with all supplies, will be rotated to ensure dispensing on a first-in-first-out (FIFO) basis.

d. Sterilized products will be transported to point of use in a covered/closed conveyance to ensure protection from contamination.

e. Sterilized products should be retained on the sterilizer rack for the amount of time it takes to adequately cool. If wrapped metal devices are placed on a cold surface while still hot, condensate will form resulting in the potential for contamination.

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f. Sterilized products must be thoroughly cooled and dry before dust covers are applied. Condensation may form on the inside of the dust cover if the package contents are too warm when the dust cover is applied. However, dust covers must be applied as soon after the cooling period as possible.

g. With each replenishment cycle, written policy and procedures will assign responsibility for a check of all designated using unit storage areas and SPD supply storage areas for outdated, damaged, or otherwise contaminated supplies. These supplies will be returned to SPD for reprocessing or disposal, as appropriate.

4. 604 Shelf Life of Sterile Items

a. Storage conditions may affect sterile item shelf life. These conditions must meet accepted standards of quality control to assist in sterility maintenance. The following is offered as guidance:

(1) Storage areas must be clean; free of dust, dirt, moisture, and vermin. This is to ensure sterilized products remaining on storage shelves for extended periods are as free from contaminating events as possible.

(2) Storage in closed cabinets offers the advantage of added package protection not available with open shelving, but is not always recommended. They are used only for items stored long-term or in areas with limited control.

(3) When open shelving is utilized, consideration must be given to clearance from walls, ceilings, and floors. Distance from ceilings must be maintained to keep sterile products from the heat of light fixtures or possible moisture from leaky overhead extinguishers. Storage away from walls and floors allows for easier cleaning of storage areas, as well as distance from potential contaminating events (18 inches from ceiling, 2 inches from outside wall and 8 inches from floor.) The bottom shelf must be solid to prevent contamination when the floor is cleaned.

(4) Sterile items should be stored under conditions limiting the potential for exposure to contaminating events. Storage conditions should be carefully controlled and provide protection from extremes in temperature and humidity. Climate control systems must be set for a temperature below 80 degrees Fahrenheit (ideally 72 degrees) and relative humidity between 35 percent and 75 percent.

(5) Sterile storage areas should remain locked and have carefully controlled traffic patterns with limited access.

b. Recommended packaging materials are those identified specifically for the purpose of sterilization of medical devices. Current examples of these materials are:

- (1) Muslin
- (2) Nonwoven Fabric
- (3) Spun-Bond Fabric
- (4) Paper/Plastic Pouches
- (5) Plastic Pouches

c. Post sterilization plastic wraps, or dust covers, should be of 2-3 mil thickness and of sufficient consistency to prevent the passage of air or moisture. Sealing must be accomplished by a means which maintains the integrity of the cover and prevents the passage of air or moisture.

d. Rigid container systems are ideal for maintaining product sterility and packaging integrity. Depending on individual manufacturer's recommendations, rigid containers are designed for extended outdates and are available in models conducive to steam or EtO sterilization. Where appropriate, products packaged in rigid containers will be considered to have a shelf life of 1-year.

e. Supplies double sequentially wrapped in products designed specifically for the sterilization of medical devices with application of a sealed plastic dust cover should be considered sterile until used or package integrity has been compromised, for up to 1-year. Products packaged in paper/plastic peel pouches should also be considered in this category.

f. Items that have a history of high use and are double sequentially wrapped in approved material should be assigned a 30-day shelf life. Items with a known high turnover rate do not need to be packaged for extended shelf life (O.R. instruments).

g. Sterility is event related, not time related. However, the longer an item remains on the shelf, the greater is the potential for exposure to a contaminating event. It is also considered poor inventory management to leave an unused item on the shelf for extended periods.

h. Any SPD processed and packaged item remaining on the shelf unused for 6 months must be evaluated for need and inventory level adjustment. At the 6-month evaluation it must be determined whether to relocate the item to a higher use area or maintain it in its present location. To assist in the effective monitoring of inventory, color codes will be assigned to each package at the time of labeling and packaging. Color codes designating specific months will be assigned as follows:

<u>Month</u>	<u>Color for 12-Month Outdate</u>
January	White
February	Purple
March	Green
April	Yellow
May	Blue
June	Gray
July	Black
August	Brown
September	Pink
October	Orange
November	Gold
December	Red

i. Color codes will be applied in a manner appropriate to accepted packaging techniques. No method will be used which may increase the potential for a break in package integrity or compromise sterility.

j. As referenced in 7176.201 of this handbook, each item sterilized by SPD will be affixed with a label indicating the six digit control number identifying the sterilizer, Julian date, and sterilizer cycle. The label will also identify the month in which the item, if not used after 1-year, will be returned to SPD for reprocessing. Items sterilized in January should be removed from service by the last day of December. Items sterilized in February should be removed from service the last day of January the following year, etc. (Exception: see paragraph f. above.)

5. 605 Sterile/Non Sterile Supply Storage

a. Sterile/nonsterile supply storage areas will be kept clean and uncluttered. The lower shelves in storage areas will be solid or either sealed to the floor or have sufficient space underneath to allow access for cleaning to avoid contamination. Top shelves and contents will be arranged so as not to obstruct the proper functioning or testing of fire detecting or extinguishing systems that are installed in or suspended from the ceiling. Shelving must be kept clean and dry. Stored materials must be far enough above the floor and away from walls to allow for adequate cleaning and avoid accidental contamination. Storage areas must be kept free of dust, dirt, moisture, insects, rodents, and vermin.

b. Supplies must be stored so as not to crush, bend, compress, or puncture the packaging or otherwise compromise the sterility of the contents.

c. Medical and surgical supplies will not be stored next to or under sinks, under exposed sewer or water pipes, or in any location where they can become wet.

d. Supplies will not be stored directly on the floor, on window sills, or in areas other than designated shelving, counters, or carts.

e. Exterior shipping cartons or corrugated boxes will be removed prior to material entering SPD or designated using unit storage areas. Shipping cartons or corrugated boxes will not be used as dispenser bins or storage containers.

f. Sterile items should be stored in carefully controlled conditions that are protective of extremes in temperature and humidity (see VA handbook 7176, Part 6,604, a. (4)).

g. Sterile storage areas should remain locked and have carefully controlled traffic patterns with limited access.

h. The automatic issue principle should be flexible enough to provide a steady flow of patient care supplies throughout the medical facility. Local SPD written policy will include a schedule for

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inspection of storage areas, stock level review of adherence to minimum inventory levels, stock level adjustment, and mandatory stock rotation. Supply items, whether processed in SPD or obtained from a commercial source, will not remain in any using unit storage area for longer than 6 months without in-depth review.

PART 7. OCCUPATIONAL SAFETY AND HEALTH

1. 700 Scope This part establishes the elements of the occupational safety and health program required to be implemented in Supply, Processing, and Distribution (SPD).

2. 701 Authority

- a. MP-3, Part III
- b. Title 29 Code of Federal Regulations (CFR) 1960, Subpart D.

3. 702 Responsibilities

a. The Chief, SPD will:

(1) Ensure that a written occupational safety and health program is developed and implemented that addresses the hazards of the environment in which SPD employees work and the tasks they are expected to perform. The program must be based on a job safety analysis conducted by an individual qualified by training and/or experience to evaluate workplace hazards and tasks and be consistent with the facility occupational safety and health program;

(2) Ensure the program has been reviewed by facility safety and/or health personnel and other appropriate officials;

(3) Ensure appropriate safety and/or health training; and

(4) Enforce safety rules, regulations, and standards.

b. Employees will:

(1) Follow safe work practices and procedures;

(2) Report unsafe conditions or practices to supervisory personnel; and

(3) Attend appropriate occupational safety and health training.

c. The facility Occupational Safety and Health Committee will approve and review annually the SPD safety and health program.

4. Program Elements. The SPD safety and health program must ensure employee involvement and must address the following:

a. Periodic occupational safety and health inspections;

b. Procedures to ensure that identified occupational safety and health deficiencies are corrected;

c. Follow-up inspections to ensure that deficiencies have been corrected.

- d. Medical surveillance for appropriate hazardous agents;
- e. Appropriate education and training programs;
- f. Procedures to limit employees exposure to hazards (i.e., engineering and administrative controls);
- g. Use of personal protective equipment;
- h. Control over regulated areas;
- i. Emergency procedures;
- j. Personal hygiene requirements; and
- k. Labeling and posting.

PART 8. EMPLOYEE TRAINING

1. 800 Scope This part establishes requirements for employee training.

2. 801 Employee Training and Documentation of Training

a. General. The Chief, Supply, Processing and Distribution (SPD), shall be responsible for the establishment of an initial orientation and recurring on-the-job training program for new and established SPD employees. This will include the SPD Level I training and completion of all text and workbook assignments (over a 20-week time frame) from the Training Manual for Central Service Technicians. Emphasis will also be placed on the following:

- (1) Principles of steam and gas sterilization.
- (2) Sterilizer and processing equipment operation.
- (3) Hazardous chemicals and Material Safety Data Sheets (MSDS) requirements for SPD.
- (4) Storage/distribution of sterile supplies.
- (5) Microbiology and infection control procedures.
- (6) SPD operational requirements (VA Handbook 7176, Part 1).

Upon completion of the text and workbook assignments, SPD employees may request to take the certification examination established by Central Office. The request must be made no later than 90 days after completing the Level I training. The certification examination will consist of a wide variety of questions and will be scored by Central Office. Participants who obtain a passing grade will receive a document of certification signed by the Deputy Assistant Secretary for Acquisition and Materiel Management. Certification can be maintained current only by the accumulation of Continuing Education Units (CEUs). Annual CEU requirements are established by SPD program officials in Central Office and, upon successful completion of the examination, CEU requirements will be issued with the certification document. Central Office SPD program officials will monitor CEU completion submitted by the Chief, SPD, for all employees.

b. The Chief, SPD, shall be responsible for the establishment of a continuous education program in which all employees will participate. Although the primary focus of the training will be on the technical aspects of SPD, emphasis will also be placed on:

- (1) Supply Management Concepts
- (2) Safety
- (3) Personnel Management
- (4) Quality Assurance
- (5) Anatomy and Physiology
- (6) Terminology
- (7) Inventory Management
- (8) Communication

A training folder will be maintained for each employee documenting course of instruction and date of attendance. A file will also be maintained outlining the training schedule and course curriculum. Participation in this training program will be considered, along with other relevant factors, in SPD promotion actions.

c. After initial assignment within SPD, but prior to the operation of EtO sterilizers or aerators, complete orientation and hands-on training must be provided for all SPD employees. This training must include:

- (1) EtO Sterilizer and Aerator Operation and Maintenance
- (2) Work Practices/Precautions for Safe Use of EtO
- (3) Safe Handling and Storage of EtO tanks
- (4) Physical and Health Hazards of EtO
- (5) Accidental Spill/Leak Plan
- (6) Emergency First-Aid Procedures
- (7) Personal Protective Equipment
- (8) Personnel EtO Monitoring Methods and the right to observe monitoring (29 CFR 1910.1047(L))
- (9) Requirements listed in 29 CFR 1910.1047(j)(3)

d. All employees who work in an area of potential exposure to EtO will be provided with information and training on EtO at the time of initial assignment to SPD and at least annually thereafter. Employees will be informed of the following:

(1) The requirements of the Department of Labor, Occupational Safety and Health Administration (OSHA), 29 CFR Part 1910, Occupational Exposure to Ethylene Oxide Final Standard, with an explanation of the contents.

(2) Any operations in their work area where EtO is present.

(3) The location and availability of the written current OSHA rule.

(4) The medical surveillance program required by the EtO final rule, with an explanation of Appendix C of 29 CFR Part 1910.

e. The medical facility must ensure that no employee is exposed to an airborne concentration of EtO in excess of 0.5 parts of EtO per million parts of air (0.5 ppm) as an 8-hour time-weighted average (TWA). A schedule of employee rotation will not be used as a means of compliance with the TWA.

f. The Chief, SPD, will review the required EtO baseline survey report as conducted by a qualified industrial hygienist. The Chief, SPD will coordinate with the responsible Service Chief, and the facility Safety and Fire Protection Engineer to ensure employee safety and compliance with the OSHA EtO standard.

g. Written outlines of all employee training programs will be maintained on file in SPD and revised as necessary. All training will be documented.

PART 9. EQUIPMENT CONTROL

1. 900 Scope. This subpart establishes requirements for control of patient care equipment issued by SPD.

2. 901 Locator and Usage Records

a. An ongoing locator and usage record will be established for each piece of patient care equipment issued by SPD. Such records help to determine if maximum usage and longevity are realized from equipment and indicate the current location of equipment in use. Records will include, but will not be limited to, the following information:

- (1) Type of Equipment
- (2) Preventive Maintenance Number
- (3) Serial number and/or nomenclature as listed on CMR (Equipment Inventory List)
- (4) Issued to (Using Area Location)
- (6) Issued by (Name)
- (7) Date Returned
- (8) Operational Remarks

b. Records will be kept current and maintained in SPD for the life of each piece of equipment.

c. A system will be devised locally to ensure that SPD is notified when equipment is transferred with the same patient to another area of the facility. Equipment control records will be promptly adjusted. All equipment issued by SPD must be returned to SPD for decontamination, disinfecting, and/or sterilization prior to use by another patient. When equipment is referred for repair or preventive maintenance, records will be annotated.

d. Where possible, equipment control data should be maintained through the use of barcoding via automation capabilities.

PART 10. COMMODITY STANDARDIZATION PROGRAM

1. 1000 Scope. This part prescribes the policies and procedures to be observed in administration of the VA Commodity Standardization Program. This program is designed to improve the quality, effectiveness and efficiency of supply support furnished to using services and to assure availability of supplies and equipment at a cost consistent with the quality required.

2. 1001 Objectives

a. Reduce the number of sizes, kinds, types, and grades of items to those essential to meet VA program requirements.

b. Maintain a uniform cataloging system consistent with the Federal Catalog System.

c. Assure economical purchasing and distribution.

d. Ensure all essential requirements of affected services are accommodated by obtaining concurrence of the using department or service head prior to standardization of the item.

3. 1002 Responsibility

a. The DAS/A&MM (90) is responsible for the Commodity Standardization Program within the VA.

b. When a department head, Associate Deputy Administrator or staff office director desires to have an item standardized, a request will be submitted to the DAS/A&MM (90) who, in collaboration with the requester, will determine the feasibility of including the item in the program.

c. Each facility will establish a Standards Committee to standardize supplies and equipment used in the medical facility and to reduce cost.